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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WILLIAMS, LEONARD M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,300	FARES ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Status of Claims

The advisory action of 7/5/2006 is hereby withdrawn. The Final Rejection of 6/30/2006 is treated as a non-final action. Examiner notes the entering of the declaration and amendment of 04/01/2005, canceling claims 1-15 and amending claims 16, 19, 20, 35, 36, 37, and 38. Claims 16-38 are currently pending

The current action is made **final.**

Response to Arguments

Applicant's arguments filed 1/3/2006 have been fully considered but they are not persuasive. The applicant's assert that the examiner has no motivation to combine the references as presented. The examiner points the applicant's to the office action of 6/30/2005 where the examiner clearly stated the reasons for the 103(a) rejection. The applicant's assert that unexpected results have been achieved and provide a declaration which was discussed at length with the applicants in the interview of 11/10/2005, the examiner agains set forth that the declaration was not sufficient to overcome the 103(a) rejection as it merely set forth the reasoning why the applicant's chose to use the pentylene glycol. The examiner clearly set forth a prima facie case of obviousness which had a different but equally valid reasoning and motivation why pentylene glycol would be used in the office action of 6/30/2005.

Response to Amendment

The declaration under 37 CFR 1.132 filed 04/01/2005 is insufficient to overcome the rejection of claims 1-38 based upon Castro et al., Cooper et al. (U.S. Patent No. 4552872), Quigley et al. (U.S. Patent No. 6075056), and Vollhardt (U.S. Patent No. 6274124) as set forth in the last Office action because: The declaration entered In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, while setting forth the reasoning as to why the applicant chose to use pentylene glycol and the effects noticed with the concurrent use of pentylene glycol with hydrocortisone, the applicant did not set forth an argument as to why the pentylene glycol/hydrocortisone combination is patentable. The examiner points out in Castro et al. that it is known in the cosmetic arts to use hydrocortisone (and other active ingredients) in cosmetic formulations and that pentylene glycol is a common cosmetic formulation ingredient, additionally Castro et al. clearly demonstrates that the pentylene glycol can be used in the formation of a variety of cosmetic compositions (specifically a mousse composition) with various other ingredients including additional alkyl glycols and solvents. Cooper et al. was used to reinforce that the hydrocortisone compounds-hydrocortisone acetate and triamcinolone

acetate, while generally taught in Castro et al., can readily be formulated into topical compositions in the presecence of alkyl glycols. Quigley et al. was simply used to demonstrate that the alkyl glycols and hydrocortisone compounds could be formulated in a variety of embodiments. Vollhardt et al. demonstrated that there were reasons to specifically use pentylene glycol in topical formulations as it imparted improved water resistance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al. (US Patent No. 6113888), in view of Cooper et al. (US Patent No.

4552872), in view of Quigley et al. (US Patent No. 6075056), and further in view of VollHardt et al. (US Patent No. 6274124).

Castro et al. teach, in col. 2 lines 35-55 and claim 21, a mousse composition for topical application that includes 0.001% to about 20% of 1,2-pentanediol and 0.001% to about 20% of 2-methyl-1,3-propanediol, in col. 4 line 60 to col. 5 line 15, Castro et al. teach dermatologically active agents that can be added to the said mousse compositions as including hydrocortisone, dexamethasone, panthenol, phenol, betamethasone, and triamcinolone.

Castro et al. teach, in col. 5 lines 48-55, examples of humectants that can be used in the compositions including glycols such as 2-methyl-1,3-propanediol, 1,2-pentanediol, hexylene glycol, and propylene glycol.

Castro et al. does not teach hydrocortisone acetate and triamcinolone acetate and their respective percentages in the compositions, nor does Castro et al. teach butylene glycol as a solvent or that butylene glycol and propylene glycol can be used together.

Cooper et al. teach, in col. 8 lines 55-63, diol compounds for use in topical pharmaceutical corticosteroid compositions including 1,2-propanediol, 1,3-propanediol, 1,2-butanediol, 1,3-butanediol, 1,4-butanediol or mixtures of these diols.

Cooper et al. teach, in col. 8 lines 10-50, corticosteroids for use in the topical pharmaceutical compositions including hydrocortisone, hydrocortisone butyrate, hydrocortisone acetate, triamcinolone, and triamcinolone acetonide. The compositions are to contain a safe and effective amount of corticosteroid from about 0.01% to about

10%, more preferably from about 0.02% to about 5%, and most preferably from about 0.05% to about 5% of corticosteroid. In examples 1-31 Cooper et al. disclose a variety of topical pharmaceutical compositions containing various corticosteroids and diols and that the compositions show enhanced penetration of the corticosteroids when applied topically.

Quigley et al., in col. 7 lines 30-65 and Table A, teach topical formulations that may be in the form of creams, ointments, gels, lotions, foams, powders, shampoos and/or liquid solutions comprising a steroid (0.01-2.5% by weight) and propylene glycol (5-20% by weight), wherein the steroid can be triamcinolone acetate.

Vollhardt teaches, in col. 3 lines 25-45, cosmetic and/or dermatological formulations comprising 1,2-pentanediol and at least one cosmetic or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin. Vollhardt details that 1,2-pentanediol should preferably represent 0.5% to 6% by weight of the composition, and that 1,2-pentanediol gives improved water resistance to the compositions as compared to 1,2-propanediol and 1,2-hexanediol.

Vollhardt teaches, in col. 3 lines 50-65, that the cosmetic and/or dermatological formulations can be in the form of an emulsion, thin lotion, creamy lotion, light cream, gel, and mousse formulations.

Vollhardt teaches, in col. 4 line 50 to col. 5 line 5, that the cosmetic and/or dermatologically active agents include steroidal anti-inflammatory agents such as

hydrocortisone, non-steroidal anti-inflammatory agents, anti-microbial agents and fragrances.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Castro et al. with Cooper et al. in view of Vollhardt.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine Castro et al. with Cooper et al. in view of Quigley et al. and Vollhardt because Castro et al. discloses topical compositions comprising 1,2-pentanediol, an additional glycol (2-methyl-1,3-propanediol), and a dermatologically active agent (which could be hydrocortisone or triamcinolone). Cooper et al. discloses topical pharmaceutical corticosteroid compositions including 1,2-propanediol, 1,3-propanediol, 1,2-butanediol, 1,3-butanediol, 1,4-butanediol or mixtures of these diols. Cooper et al. discloses that the topical pharmaceutical corticosteroids used in the compositions include hydrocortisone, hydrocortisone butyrate, hydrocortisone acetate, triamcinolone, and triamcinolone acetonide. Quigley et al. teach topical formulations of triamcinolone acetate and propylene glycol. Vollhardt teaches cosmetic and/or dermatological formulations comprising 1,2-pentanediol and at least one cosmetic or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin. Vollhardt teaches that the cosmetic or dermatologically active agent can be a steroidal anti-inflammatory such as hydrocortisone. Vollhardt also discloses that 1,2-pentanediol confers greater water resistance to compositions. It would have been obvious to one of ordinary skill in the art at the time the invention was made that 1,2-pentanediol could be used in the topical

pharmaceutical corticosteroid compositions of Cooper et al., in view of Vollhardt, as Castro et al. demonstrated that 1,2-pentanediol could be combined with another diol (propylene glycol or butylenes glycol or both) and that Castro et al., Cooper et al. and Vollhardt's compositions all contain the same dermatologically active agents (steroidal anti-inflammatories). Quigley et al. demonstrate that triamcinolone acetate is an acceptable steroidal anti-inflammatory for glycol formulations. The increased water resistance properties of 1,2-pentanediol containing compositions would motivate one of ordinary skill in the art to combine the compositions. A reasonable chance of success would be expected as the compositions demonstrate that 1,2-pentanediol can be combined with additional diols and all the compositions detailed include steroidal anti-inflammatory agents exemplified by hydrocortisone.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER